



**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

July 28, 2005

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety & Applied Nutrition
Food & Drug Administration
5100 Pain Branch Parkway
College Park, MD 20740

Re: Nutramax Laboratories, Inc.
30-Day Notice under 403(r)(6) of DSHEA

Dear Madam/Sir:

This letter is being submitted pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 codified at 21 U.S.C. ' 343(r)(6) by Nutramax Laboratories, Inc., located in Edgewood, Maryland.

As required by 21 CFR ' 101.93(a)(2) Nutramax Laboratories submits the following information:

- (i) The name and address of the distributor of the dietary supplement that bears the statements:

Nutramax Laboratories, Inc.
2208 Lakeside Boulevard
Edgewood, Maryland 21040

2005-7057
Aims

- (ii) The text of the statements that are being made are as follows:

"Coenzyme Q₁₀ is an antioxidant and is essential for the conversion of the food we eat into energy."

"Organs that have tremendous energy requirements, such as the brain and heart, possess much greater numbers of the energy-producing mitochondria and thus need greater quantities of coenzyme Q₁₀."

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Comax 30 Day Notice final 072805

2208 Lakeside Boulevard • Edgewood, Maryland 21040
410-776-4000 • Fax 410-776-4009 • Toll-free 800-925-5187 • www.nutramaxlabs.com

Office of Special Nutritionals (HFS-450)

July 28, 2005

Page 2

"With age, the level of coenzyme Q₁₀ has been found to decrease, affecting the body's energy production."

"Coenzyme Q₁₀ is a fat soluble vitamin like compound that functions as an important antioxidant."

"Coenzyme Q₁₀ is found throughout the body with the highest concentration in the cells of organs that require large amounts of energy such as the heart."

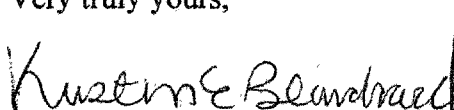
"A number of different vitamins, minerals and amino acids are required for the forming of coenzyme Q₁₀ in the body. Various factors including aging, genetics and cholesterol lowering statins, can lead to a coenzyme Q₁₀ deficiency."

- (iii) The dietary ingredient that is the subject of the statements is coenzyme Q₁₀.
- (iv) The statements appear on the labeling of the dietary supplement marketed under the brand name CoMax Q10®.

I hereby certify that the information contained in this notice is complete and accurate, and that Nutramax Laboratories has substantiation that the statements in this notice are truthful and not misleading.

If you have any questions regarding this notification, please contact us.

Very truly yours,



Kristen E. Blanchard
Vice President, Legal & Government Affairs